Health Information Technology Policy Committee
Final
Summary of the May 11, 2011, Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 23rd meeting of the Health Information Technology Policy Committee (HITPC). She reminded the group that this was a Federal Advisory Committee meeting being conducted with the opportunity for public comment, and that a transcript would be made available on the ONC Web site. She asked Committee members to introduce themselves, and turned the meeting over to National Coordinator for Health Information Technology Farzad Mostashari.

2. Opening Remarks

Mostashari welcomed the group, noting that over the summer, important work will be carried out in defining the HIT agenda and in the areas of policy and standards. He reflected on the issues Committee members would be discussing during the meeting in the context of how they align with the principles guiding the overall vision.

Regarding their first discussion about meaningful use he pointed out that tension exists between the two principles of "keeping their eyes on the prize" and "keeping their feet on the ground." The Committee must be clear on it wants the field to move while also recognizing where the field is today. There is a need to be evidence-based, live in the real world, take incremental steps, and work backward from goals of the framework. It is important to maintain momentum and progress by making the HIT incentive program inviting and inclusive. Participation must be feasible for new organizations that are just now beginning implementation and understanding the workflow changes. There is a certain trajectory that must be maintained in terms of advancing technology and standards to reach the 2016 goals.

At the last HITPC meeting, there was significant realization that HIT and the incentive program do not live in a vacuum, but are part of a larger environment of health care system transformation. This group does not have to take on everything, but the Committee does need to make it possible for some of the other innovations to take place. No organization should have to make a choice between preparing for accountable care or preparing for meaningful use.

Mostashari explained that the Usability Workgroup is examining the question of using the dynamism and the innovation of the marketplace to help facilitate a minimum level of government intervention. What are the minimum actions necessary that can be taken to make markets more perfect? How do they not stifle innovation while making sure that markets work as well as they possibly can?

Finally, Mostashari touched on the theme of the putting patient at the center of everything: this has served the Committee well in every discussion. The Privacy and Security Tiger Team is at the front of this effort. It is clear that they cannot compromise, and will do everything possible to protect patients' privacy and the security of their information.

3. Review of the Agenda

HITPC Chair Paul Tang called for a motion to approve the minutes from last month's HITPC meeting; the minutes were approved by consensus. Then, he introduced Joshua Sharfstein, the Secretary of Health and Mental Hygiene for the State of Maryland, a new Committee member who will be representing the public health perspective. Sharfstein previously served as Principal Deputy Commissioner for the U.S. Food and Drug Administration (FDA).

Sharfstein pointed to the tremendous opportunities that HIT creates in the public health sector both to understand what is going on and then intervene in a way that might save people from illness and death.

> **Action Item #1:** Minutes from the April 13, 2011, HITPC meeting were approved by consensus.

4. Meaningful Use Workgroup: Stage 2 and Timing

Meaningful Use Workgroup Chair Paul Tang reviewed the hearings that the group held in 2010 that provided information that was used to develop draft recommendations in December. The Workgroup has been reviewing the comments received from a February Request for Comment (RFC), and at this meeting they presented a set of draft recommendations for Stage 2.

Tang began the presentation of the draft Stage 2 objectives, which are divided into five categories: (1) improving quality, safety, efficiency, and reducing disparities; (2) engaging patients and families; (3) improving care coordination; (4) improving population and public health; and (5) ensuring privacy and security protections. Tang then presented the objectives related to improving quality, safety, efficiency, and reducing disparities.

Discussion

- Regarding drug-drug interaction checking, Carl Dvorak asked if it would be possible to get a nationally standardized list of overrides as soon as possible to avoid change management problems. Tang indicated that this activity would be moved to the HIT Standards Committee (HITSC) as soon as possible so that they can either point to an appropriate list (if one exists) or begin developing one soon.

- In response to a question about whether these objectives would apply to both Medicare and Medicaid practitioners, Farzad Mostashari reminded the group that some of the Medicaid providers will still only be at Stage 1 when these Stage 2 objectives come out, so these will not immediately apply.

- One Committee member commented that the more specific the Workgroup can be with regard to new terminology, the easier and it will be for those trying to meet these requirements.

- Another Committee member asked if it would be more effective to narrow the focus to being able to exchange the data that already exists, or whether there are key things missing such that if exchange was possible it would not be very useful. Tang said that a decision will need to be made about that balance after this meeting's discussions and the May 13 hearing that will include specialists and field experiences.

- Regarding drug-drug interaction, Paul Egerman explained that it will be important to find a way to implement this feature without adding keystrokes for every alert. Tang acknowledged this, and commented that the Workgroup will need to consider what the user gets in return for a keystroke. For example, once a user responds to a system, the system will learn. He pointed to work from the University of Utah showing that putting guidelines into place with a good feedback system creates a useful system in a very short period of time. Usability comes into play every time something is proposed.

- Dvorak suggested that hospitals be held accountable for electronically returning 40% of those orders that were sent electronically in a structured format where available (given that not all test results have a Logical Observation Identifiers Names and Codes [LOINC] code).

- Gayle Harrell cautioned the group about making the electronic lab transmission objective a core versus menu option. There are many labs that do not have the capability to send structured data back. Many will have to hand enter the information. Her preference is for this to stay as a menu option. Also, if they are moving towards LOINC, they need to send a strong message that LOINC is the preferred mechanism, especially for hospital labs.

- With regard to advanced directives, Egerman commented that the intention is good, but implementation will be very difficult. Christine Bechtel said that part of their original thinking was akin to smoking status being recorded—it is about supporting the conversation and getting more advanced directives going in the health care system, and then moving that data around. She agreed that this needs more work and suggested that the population could be broadened by removing the age limit.

- Larry Wolf explained that the movement towards standards will take a lot of time and a clear roadmap. If LOINC is to be the standard for labs, then ways to build a transition are needed. Historically, systems are built using local codes; moving away from this represents a challenge. This is a core problem that will require a great deal of thought as to approaches for moving ahead in an effective way. The signal must be clear: new systems must use LOINC for labs. Existing labs will need a bridge.

- Neil Calman pointed out that there needs to be delineation between specialties and different requirements from one to another in terms of advanced directives.

- Marc Probst asked whether a lab system is part of the scope of an EHR with regard to meaningful use. Mostashari indicated that there is a meaningful use requirement around reporting notifiable lab conditions to public health agencies. The ability to generate these kinds of messages is a part of certification. Whatever system a provider uses to do this would need to be certified for performing that action.

- Dvorak pointed out that many hospital labs run a separate reference lab line of business, conducting lab tests on patients they never actually see. These labs really do operate independently and this is going to be perceived as an indirect lever: their EHR money will be withheld for an objective that they are not fulfilling in this other line of business. He suggested that this issue be given future consideration. Egerman commented that he sees the lab as a separate department, or module, from a certification standpoint. Although some have separate lab information systems, others are integrated with what the hospital system already does. The requirement that hospitals be able to transmit labs is very important and a major step forward for information exchange. He acknowledged Dvorak's concerns and noted that there is no policy lever over commercial labs. There is a policy lever for hospitals, however, and the Workgroup is using it.

- Several Committee members acknowledged that meaningful use scope creep will be an issue that keeps coming up.

- Egerman noted that this category of objectives includes health care disparities and asked about the status of health disparities in the context of Stage 2. Tang pointed to quality reporting and setting up for dealing with disparities by reporting them in a more granular format.

- Larry Wolf noted that team-based care, with multiple providers interacting, is an evolving model for care that has tremendous implications for the model being used currently to consider how caregivers interact.

- Regarding electronic notes, Probst said that the International Classification of Diseases 10 (ICD-10) will significantly change how notes are taken. He suggested the Workgroup consider what it is asking people to do and how that aligns timing-wise with the adoption of ICD-10.

Following these comments, George Hripcsak presented the objectives related to engaging patients and families.

Discussion

- In response to a comment from Carl Dvorak, Christine Bechtel clarified that the objective should indicate that "patients view and *have the ability* to download their information." That capability must be a part of this function, in that they are trying to address the fact that a patient may have a number of different sources of health information. They need to be able to download and aggregate their information somewhere, if they choose.

- It was noted that in Stage 1, any electronic media, including USB drives and CDs, were included in the "view and download" function. For many reasons, this is not the direction in which the Workgroup wants to move, and it is considering removing this option from the "view and download" function. The patient will still have the option to choose paper records. Dvorak suggested that those who have access to a "download" button should have to go through extra steps to make sure they understand what happens when they download information onto their own hard drives to avoid compromising their privacy.

- Bechtel pointed out that the measurement for Stage 1 was that 10% of patients actually access their health information. If a provider really wants 10% of their entire panel to log on one time during the course of the measurement period, then that provider needs to engage patients in some way that is more significant than just putting an informational poster up on the waiting room wall. Gayle Harrell commented that certain populations have a low threshold of people with the capability to view things electronically. This will put a huge burden on many clinics and federally qualified community health centers that, given the digital divide that exists, may have significant issues in educating their clientele and in the clientele having the ability to access that information electronically.

- Josh Sharfstein asked whether text messaging is an option for patient discharge instructions. Hripcsak suggested that the discharge instructions may be too voluminous for a text message, but suggested that it would be good to look into sending text reminders with regard to some of the discharge instructions.

Next, Hripcsak presented the objectives related to improving care coordination.

Discussion

- Larry Wolf pointed out that long-term care has traditionally meant nursing homes, and he thinks that the intent in this context is broader: "long-term and post-acute care" may be a more effective way of expressing this sentiment. There has been a lot of discussion about longitudinal health care plans, and he has concerns about including them in Stage 2. Hripcsak commented that the Workgroup considered merging the summary field with the plan and patient engagement fields as a practical way to do so for now.

- Bechtel suggested that it would be helpful to present more clarity on data fields at the next HITPC meeting.

- Dvorak urged that the care plan be moved out of Stage 2. He commented that it is important and needs to be done well, and strongly suggested that the Workgroup move it to Stage 3.

- Harrell said that care coordination is one of the most important issues the Workgroup is considering. Under the legislation however, long-term care is not within their purview. There are not meaningful use objectives for long-term care, nor are long-term care providers being incentivized to purchase EHRs. Hripcsak pointed out that the Workgroup wants to expand credit for hospitals so that if hospitals engage in care coordination with long-term care centers, hospitals will get credit for doing so.

- Deven McGraw pointed out that the intent is to allow exclusions for those who cannot electronically exchange, and that would mean not only that a provider's state does not have an HIE but that they cannot use NHIN Direct. Exclusions are being allowed in situations for which there is a physical impossibility of exchanging.

- David Lansky expressed concern about the desire to see advanced performance on the quality measurement side. A number of measures around efficiency require imaging data to be available, but if the bar is being set too for capturing data in the record, then users will not be able to apply clinical decision support to it. He suggested that work is needed to harmonize across multiple arms of the program with a view toward Stage 3 so that the overall Congressional intent is supported.

Hripcsak then presented the objectives in the area of population and public health.

Discussion

- It was pointed out that there is some variability in how states wish to receive public health information, but there are current standards available for immunizations and for electronic lab reporting in HL-7. In addition, the Centers for Disease Control and Prevention (CDC) has provided syndromic surveillance standards.

- One Committee member suggested that a standard be named for each area, and that hospitals should be held accountable for sending the information in a standard format.

Next, Hripcsak presented the privacy and security objectives, after which Tang discussed the timing of the meaningful use stages. He presented three timing options for Stage 2: (1) maintain the current timeline and a 1-year EHR reporting period, (2) maintain the current timeline and permit a 90-day EHR reporting period, or (3) delay the transition from Stage 1 to Stage 2 by 1 year (which affects only those providers who begin the meaningful use program in 2011).

Discussion

- Bechtel asked whether early entrants would receive payments for simply doing another year of Stage 1, or if payment would be held until they reached Stage 2. Tang said that early entrants would continue to get their third-year payment for meeting Stage 1 criteria.

- Paul Egerman said that the idea that Stage 2 for some providers would be just 1 year is very problematic. To make large changes once per year is very difficult and expensive for both providers and vendors. He expressed concern that option 3 is selected and Stage 2 is extended out for 1 year, then Stage 2 will be continually refined in the interim and it may not resemble the way it currently is envisioned. He suggested adopting options 1 or 2, and reducing the scope of what will be included in Stage 2.

- Dvorak suggested option 3, or a Stage 2 with a reduced scope, perhaps mostly ratcheting up percentages that are already in place. He also suggested convening a customer-oriented panel.

- One Committee member noted that he was at a meeting with 30 prominent health care CEOs the week before this meeting. Each company represented has a mature EHR system. Less than 20% of them plan on attesting in 2011; 90% of that group is feeling undue pressure on their ability to meet meaningful use. They are feeling pressure not just because of meaningful use, but also because of ICD-10.

- Larry Wolf noted that barcode medication administration carries tremendous value, but is also a very complicated endeavor.

- Bechtel pointed out that late adopters of Stage 1 will actually be using Stage 2 or Stage 3 certified products. She asked, why would they not be asked to do some of the things that they will be capable of doing once they have their system in place?

5. Certification/Adoption Workgroup: Report on Usability Hearing

Certification/Adoption Workgroup Chair Marc Probst and Committee member Larry Wolf presented the group's findings from the recent EHR usability hearing convened by the Certification/Adoption Workgroup. Wolf commented that Mostashari was clear at the hearing that this was not going to be the only time issues of usability are addressed. The ONC wants to have good oversight in this area, with meaningful measurements. The first panel featured care providers and included the following major themes:

- Time is precious, whether it is counting keystrokes or time spent with patients. Usability is key to saving time.

- Cognitive load, including disabilities, must be considered for practitioners and for patients. There are many styles of interacting with computers, and systems need to support a variety of these interaction styles.

- Collaborative care is an important theme. Multiple clinicians might be working with a patient. How does the system support their collaboration?

- Complexity exists in many areas, such as feedback loops (e.g., the possibility of including quicker user education when a user gets stuck); multi-vendor /multi-system issues in terms of usability, interoperability, and safety; switching costs (i.e., systems are so expensive that organizations are not going to switch once they have done an installation; and care complexities.

- These issues relate to more than just the user interface—interoperability relates to the whole system, and the system of systems that are at work in a practice setting.

The second panel dealt with consumer issues. The following themes emerged: (1) meet the information needs of the consumer, (2) collaborative care and the role of the consumer, (3) privacy and security, (4) consumer expectations are on the rise, and (4) use caution when repurposing data.

The third panel included technology developers. The themes from this panel included the following: (1) usability is important, (2) assessing usability is part of development, (3) local customization/implementation, (4) assess usability in context after implementation, and (5) regulation (there are a spectrum of views on this issue). This panel and the discussions associated with it led to messages ranging from "we need a lot of flexibility" to "we need a lot of standards." The universal agreement, though, was the importance of usability, and vendors are seeing this as a key differentiator. User interface is what people understand as the product, so vendors they see it as important to get right. Having said that, vendors build these systems, test them, bring them through certification, and then when they are implemented, by their very nature they need to be configured for variable health care settings. So what gets implemented in the health care setting is not what the vendor built. All of the choices that are made during configuration about workflow can increase or decrease usability.

The fourth panel involved measuring and improving usability and featured discussions on the science of usability testing and an abstract framework for assessing usability (both process and technical evaluation). Wolf commented that the most important thing that came out of this panel is that there is a growing sense of the provider community and the testing community. As much as they were at odds at the hearing in some ways, Wolf feels that they are beginning to come together. There will be a workshop sponsored by the National Institute of Standards and Technology in approximately 1 month on this issue, where hopefully there will be more progress.

In the fifth panel, usability options were discussed. Major themes included: (1) current testing and feedback, (2) one size cannot possibly not fit all, (3) the importance of design, and (4) experimental design options.

Discussion

- Committee members suggested that at future hearings, more full-time, working physicians and more patients be included.

- It was noted that the physical configuration of the exam room is critically important. If a provider spends more time with the computer than with the patient, or if the patient cannot see what is on the screen, those are significant issues.

- Paul Egerman pointed out that each person has his or her own definition of usability, depending on their perspective. He asked, what is the role of government in this process? How can they create a marketplace for all of these things to evolve?

- Gayle Harrell noted that some providers have real concerns about whether all of this is worth the amount of time and money they are spending on it. Both patients and providers are frustrated.

- Paul Tang asked about the issue of usability affecting safety. Wolf said that the general feedback about usability affecting safety had to do with cognitive load. How does the practitioner find what is relevant? Whether it was training or access to data, it was thematic that safety was impacted by usability, but the definition of usability was broad.

- Carl Dvorak suggested that they think about usability all the way back to meaningful use requirements. Smoking cessation requirements are one example of a meaningful use objective that will translate into a usability issue.

6. Information Exchange Workgroup: Individual-Level Provider Directories

Information Exchange Workgroup Chair Micky Tripathi presented what are hoped to be the group's final recommendations on individual-level provider directories (ILPDs). Tripathi provided background on the Workgroup's strategy, which was to separate out entity-level provider directors (ELPDs) versus ILPDs, and to connect ILPD use cases and links to ELPDs. The Workgroup formulated two types of recommendations—policy guidance and best practices—in the following four domains: (1) content, (2) functionality, (3) security access and audit, and (4) immediate policy levers.

The Workgroup has been hearing about the urgent need for these guidelines, particularly from state-level organizations, health information exchanges (HIEs), and Beacon programs, which are specifically charged with creating directories. Tripathi showed an illustration of how ILPDs would interact with ELPDs, and a mapping between the two. Then, Tripathi discussed the areas that the recommendations do not cover: governance, business model, and responsible parties for the directories. Although these are important questions/issues, the Workgroup would need more guidance and a structured framework in order to address them.

Tripathi presented the Information Exchange Workgroup's recommendations for ILPDs and opened the floor for discussion.

Discussion

- Cark Dvorak asked if anything could be done to signal that one standard ILPD interaction and one set of guidance would be tolerated. If a standard of "no ripping and replacing" is set, it will create a difficult situation for standardization. Instead, shouldn't the Workgroup be sending a signal that there will be one set of standards and people will need to quickly get on board?

- In response to a concern voiced by Gayle Harrell, Deven McGraw reminded the Committee that the Privacy and Security Tiger Team has a set of recommendations on digital certificates at the entity level. The Team is now moving into the phase of defining criteria for those

entities that get to deliver the certificates. This work needs to be married up with the set of policies that deals with authentication.

- Tripathi noted that in California, there will be a central certificate authority for entities and providers. Licensed professionals and administrative staff will be under the umbrella of entities, so there is an explicit chain of trust. How does that roll up to the national level?

- McGraw commented that these efforts creep into the work of the HIT Standards Committee, in terms of trying to decide when a single standard is necessary versus sticking to policy functions.

- Egerman suggested that the Nationwide Health Information Network (NWHIN) governance standards could deal with the comments made by Harrell and McGraw. He proposed changing recommendation 4B to reference NWHIN governance standards.

- Art Davidson suggested that recommendation 4E should read "HHS should consider" rather than limiting it only to CMS. In this way, it is framed more broadly as a federal initiative.

Action Item #2: The Committee approved the Information Exchange Workgroup's Recommendations on ILPDs, with the following two modifications:

- Recommendation 4B will reference NWHIN governance standards.
- Recommendation 4E will be modified to include HHS and not just CMS.

7. Privacy and Security Tiger Team Update

Privacy and Security Tiger Team Chair Deven McGraw noted that on the group's last call, it discussed the next set of topics it will take on—she also said that there is an open comment section on the FACA blog for the public to comment on the Team's next topics.

The Team needs to finish up with the push transactions recommendations, and it has not yet addressed patient and organizational issues regarding data amendment. Other issues that came up include the privacy and security issues related to query and response, or the pull model. There are also issues associated with hosted EHRs, and transparency issues with patient portals. ONC is working on a gap analysis under the Health Insurance Portability and Accountability Act (HIPAA) Security Rule. The Tiger Team will review this analysis and its findings when it is complete. The topic of unauthorized internal access also need to be addressed.

Tiger Team Co-Chair Paul Egerman indicated that the group is also taking up issues relating to digital certificates. Last November, they made recommendations about digital certificates at an entity level, having to do with making sure entities are who they said they are. The HITPC asked for some clarifications on certificates of authority. What are the qualifications of those

organizations? This raises the issue involving the federal bridge and communicating with federal government agencies. The Team has established a task force to address that issue, with support from Debra Lansky and Carl Dvorak. The task force has a goal of getting recommendations back to the Tiger Team and then the HITPC for its June meeting.

Discussion

- Paul Tang noted that a number of health plans have started acquiring data exchange companies. This will allow them to get information from one place to another, but the thought is that they might do something with the data in the middle. He wondered whether this was of concern to the Tiger Team. McGraw indicated that this is an issue of concern to the Team.

- Harrell asked whether there will be an individual-level certificate. Egerman said that this is currently unknown. McGraw said the expectation is the certificate will be held at the entity level. This is why the ILPD is so tightly linked with the ELPD. Harrell stressed that this needs to be clarified.

8. Public Comment

- Dr. Richard Singerman from TrustNetMD comment on user interfaces, saying that major safety studies need to be conducted. He explained that when one rents a car, the accelerator is always on the right, and the brake is always on the left—the same thing cannot be said for EHR systems. He offered an example of a patient he knows personally who nearly had the wrong side of his neck operated on because an image in the system was reversed. One can wonder about the opportunities for harm when a physician is given a device that was not certified in its final configuration.

- Chantal Worzala from the American Hospital Association (AHA) appreciated the consideration the Committee is giving to a delaying Stage 2. She said this is important and necessary in order to make sure that Stage 2 is done well and safely for patients. Providers do not think that Stage 2 needs to be redefined just because of a time period extension. She suggested that a delay in Stage 2 be combined with a 90-day testing period. Vendors need to roll out products to all of their customers—that includes a great deal of work. In addition, hospitals cannot maintain this pace and keep things safe for patients. She reminded the Committee that there is a 50 percent increase of objectives from Stage 1 to Stage 2 of meaningful use.

- Mike Apple from McKesson also appreciated discussion regarding Stage 2 timing and the additional areas where the Committee was clear and specific regarding Stage 3 criteria. He urged the HITPC to focus on the 3 months that follow the June recommendations on Stage 2, with an emphasis on reviewing every item for Stage 3 in the Notice of Proposed Rulemaking. In this way, the Committee can obtain feedback now and be better prepared for Stage 3.

- Jason Bird from The American Society of Anesthesiologists (ASA) spoke to raise awareness about that group's dilemma. In stage 1, when the regulations came out, many thought that

anesthesiologists would be exempted, but in fact most will be included in incentive payments, which they welcome. However, many of the measures are not applicable to this practice. The ASA has submitted letters and a comprehensive chart that identifies recommendations and clarifications that will allow anesthesiologists to be included. Their inclusion is critical because anesthesiologists are the bridge from the pre- to the post-operative setting.

- Matt Quinn from NIST explained that there is an ISO definition of usability: ISO 9241. He also announced a NIST workshop on June 7 to gain constructive technical feedback on draft usability protocol, as well as to build a collaborative community to advance the science in this field.

- Lauren Fifield spoke as a representative of Athena Health, which is a provider of software-enabled services. Their CEO has gone so far as to guarantee meaningful use payments, and they are now ushering all of their meaningful use providers through the measures. She said she understands that other models of software require extensive modifications. However, using the cloud model of software they are able to deploy Stage 2 certified software with no additional cost. With regard to the meaningful use timing issue, she supports option 1 or 2. She agrees with the concept of an evolving Sage 1 and asked that the Committee keep in mind that at the end of the day software and training can only go so far.

- Lindsey Hagel from the American Dietetic Association issued a plea that the Committee not back away from allowing consumer download and viewing for privacy and security reasons. Regarding standards, she pointed to the complexity of who owns which standards. She encouraged a gap analysis on standards to evaluate which ones have models that can be used now, and to put some on the radar for Stage 3, including some for food allergies, which can be as dramatic as drug allergies.

- Mark Siegel from GE Healthcare said that meaningful use timing option 3 is feasible. He also agreed with having a 90-day reporting period for each new stage. He commented that the new proposal to provide some summaries of care electronically is terrific, and the 10% level for hospitals is appropriate. Regarding eligible professionals: efficient measurement of this measure is important, but given the importance of this measurement for exchange, he is concerned that 25 exchanges is insufficient. He suggested applying the 10% level to both hospitals and eligible professionals.

SUMMARY OF ACTION ITEMS:

Action Item #1: Minutes from the April 13, 2011, HITPC meeting were approved by consensus.

Action Item #2: The Committee approved the Information Exchange Workgroup's Recommendations on ILPDs, with the following two modifications:

- Recommendation 4B will reference NWHIN governance standards.
- Recommendation 4E will be modified to include HHS and not just CMS.